CLAIMS

1. An isolated polypeptide comprising at least 7 consecutive amino acid residues of human mammaglobin, wherein the consecutive amino acid residues are present within a sequence selected from the group consisting of IDELKECFLNQTDETLSNVE (Pro2; SEQ ID NO: 1); TTNAIDELKECFLNQ (Pro2-3; SEQ ID NO: 2); SQHCYAGSGCPLLENVISKTI (Pro5; SEQ ID NO: 3) EYKELLQEFIDDNATTNAID (peptide 5A; SEQ ID NO: 4) and KLLMVLMLA (mgb 1; SEQ ID NO: 5), and wherein no more than 30 consecutive residues of human mammaglobin are present within the polypeptide.

2. The polypeptide of claim 1 wherein the polypeptide comprises at least 9 consecutive amino acid residues of human mammaglobin.

3. The polypeptide of claim 1 wherein the polypeptide comprises at least 15 consecutive amino acid residues of human mammaglobin.

4. The polypeptide of claim 1 wherein the polypeptide comprises the amino acid sequence TTNAIDELKECFLNQ (Pro2-3; SEQ ID NO: 2).

5. A pharmaceutical composition comprising a polypeptide according to claim 1, in combination with a physiologically acceptable carrier.

6. A vaccine comprising a polypeptide according to claim 1, in combination with an immunostimulant.

7. The vaccine of claim 6 wherein the immunostimulant is an adjuvant.

8. An isolated antibody, or antigen-binding fragment thereof, that specifically binds to a mammaglobin epitope having the sequence TTNAIDELKECFLNQ (Pro2-3; SEQ ID NO: 2).

9. A pharmaceutical composition comprising an antibody or fragment thereof according to claim 8, in combination with a physiologically acceptable carrier.

10. A method for inhibiting the development of breast cancer in a patient, comprising administering to a patient an effective amount of a polypeptide according to claim 1, and thereby inhibiting the development of breast cancer in the patient.

11. A method for inhibiting the development of breast cancer in a patient, comprising administering to a patient an effective amount of an antibody or antigen-binding fragment thereof according to claim 8, and thereby inhibiting the development of breast cancer in the patient.

12. A method for determining the presence or absence of breast cancer in a patient, comprising the steps of:

(a) contacting a biological sample obtained from a patient with an antibody or antigen-binding fragment thereof according to claim 8,

(b) detecting in the sample an amount of polypeptide that binds to the antibody or antigen-binding fragment thereof; and

(c) comparing the amount of polypeptide to a predetermined cut-off value, and therefrom determining the presence or absence of breast cancer in the patient.

13. The method of claim 12 wherein the antibody is a monoclonal antibody.

14. The method of claim 12 wherein step (b) comprises contacting bound polypeptide with a second antibody that specifically binds to a mammaglobin epitope.

15. The method of claim 14, wherein step (b) further comprises comparing a signal obtained from the second antibody with a standard curve.

16. A method for determining the presence or absence of breast cancer in a patient, comprising the steps of:

(a) contacting a biological sample obtained from a patient with a polypeptide according to claim 1,

(b) detecting in the sample an amount of antibody that binds to the polypeptide; and

(c) comparing the amount of antibody to a predetermined cut-off value, and therefrom determining the presence or absence of breast cancer in the patient.

17. A method for monitoring the progression of breast cancer in a patient, comprising the steps of:

(a) contacting a biological sample obtained from a patient at a first point in time with an antibody or antigen-binding fragment thereof according to claim 8;

(b) detecting in the sample an amount of polypeptide that binds to the an antibody or antigen-binding fragment thereof;

(c) repeating steps (a) and (b) using a biological sample obtained from the patient at a subsequent point in time; and

(d) comparing the amount of polypeptide detected in step (c) to the amount detected in step (b) and therefrom monitoring the progression of breast cancer in the patient.

18. The method of claim 17, wherein the antibody is a monoclonal antibody.

19. The method of claim 17, wherein step (b) comprises contacting bound polypeptide with a second antibody that specifically binds to a mammaglobin epitope.

20. The method of claim 19, wherein step (b) further comprises comparing a signal obtained from the second antibody with a standard curve.

21. A method for monitoring the progression of breast cancer in a patient, comprising the steps of:

(a) contacting a biological sample obtained from a patient at a first point in time with a polypeptide according to claim 1;

(b) detecting in the sample an amount of antibody that binds to the an antibody or antigen-binding fragment thereof;

(c) repeating steps (a) and (b) using a biological sample obtained from the patient at a subsequent point in time; and

(d) comparing the amount of antibody detected in step (c) to the amount detected in step (b) and therefrom monitoring the progression of breast cancer in the patient.

22. A diagnostic kit, comprising:

(a) one or more antibodies or antigen-binding fragments thereof according to claim 8; and

(b) a detection reagent comprising a reporter group.

23. The kit of claim 22, wherein the detection reagent is an antibody that specifically binds mammaglobin.

24. A diagnostic kit, comprising:

(a) one or more antibodies or antigen-binding fragments thereof according to claim 8; and

(b) recombinant mammaglobin.

25. The kit of claim 22 or claim 24, wherein the antibodies are immobilized on a solid support.

26. The kit of claim 25, wherein the solid support comprises nitrocellulose, latex or a plastic material.

27. The kit of claim 22, wherein the detection reagent comprises an immunoglobulin, anti-immunoglobulin, protein G, protein A or lectin.

28. The kit of claim 22 wherein the reporter group is selected from the group consisting of radioisotopes, fluorescent groups, luminescent groups, enzymes, biotin and dye particles.

29. A diagnostic kit, comprising:

(a) one or more polypeptides according to claim 1; and

(b) a detection reagent comprising a reporter group.

30. The kit of claim 29 wherein the polypeptides are immobilized on a solid support.

31. The kit of claim 30 wherein the solid support comprises nitrocellulose, latex or a plastic material.

32. The kit of claim 29 wherein the detection reagent comprises an immunoglobulin, anti-immunoglobulin, protein G, protein A or lectin.

33. The kit of claim 29 wherein the reporter group is selected from the group consisting of radioisotopes, fluorescent groups, luminescent groups, enzymes, biotin and dye particles.

34. An isolated antibody, or antigen-binding fragment thereof, that specifically binds to glycosylated mammaglobin.

35. A pharmaceutical composition comprising an antibody or fragment thereof according to claim 34, in combination with a physiologically acceptable carrier.

36. A method for inhibiting the development of breast cancer in a patient, comprising administering to a patient an effective amount of an antibody or antigen-binding fragment thereof according to claim 34, and thereby inhibiting the development of breast cancer in the patient.

37. A method for determining the presence or absence of breast cancer in a patient, comprising the steps of:

(a) contacting a biological sample obtained from a patient with an antibody or antigen-binding fragment thereof according to claim 34,

(b) detecting in the sample an amount of polypeptide that binds to the antibody or antigen-binding fragment thereof; and

(c) comparing the amount of polypeptide to a predetermined cut-off value, and therefrom determining the presence or absence of breast cancer in the patient.

38. The method of claim 37 wherein the antibody is a monoclonal antibody.

39. The method of claim 37 wherein step (b) comprises contacting bound polypeptide with a second antibody that specifically binds to a mammaglobin epitope.

40. The method of claim 39 wherein step (b) further comprises comparing a signal obtained from the second antibody with a standard curve.

41. A method for monitoring the progression of breast cancer in a patient, comprising the steps of:

(a) contacting a biological sample obtained from a patient at a first point in time with an antibody or antigen-binding fragment thereof according to claim 34;

(b) detecting in the sample an amount of polypeptide that binds to the an antibody or antigen-binding fragment thereof;

(c) repeating steps (a) and (b) using a biological sample obtained from the patient at a subsequent point in time; and

(d) comparing the amount of polypeptide detected in step (c) to the amount detected in step (b) and therefrom monitoring the progression of breast cancer in the patient.

42. The method of claim 41 wherein the antibody is a monoclonal antibody.

43. The method of claim 41, wherein step (b) comprises contacting bound polypeptide with a second antibody that specifically binds to a mammaglobin epitope.

44. The method of claim 43, wherein step (b) further comprises comparing a signal obtained from the second antibody with a standard curve.

45. A diagnostic kit, comprising:

(a) one or more antibodies or antigen-binding fragments thereof according to claim 34; and

(b) a detection reagent comprising a reporter group.

46. The kit of claim 45 wherein the detection reagent is an antibody that specifically binds mammaglobin.

47. A diagnostic kit, comprising:

(a) one or more antibodies or antigen-binding fragments thereof according to claim 8; and

(b) recombinant mammaglobin.

48. The kit of claim 45 or claim 47, wherein the antibodies are immobilized on a solid support.

49. The kit of claim 48, wherein the solid support comprises nitrocellulose, latex or a plastic material.

50. The kit of claim 45, wherein the detection reagent comprises an immunoglobulin, anti-immunoglobulin, protein G, protein A or lectin.

51. The kit of claim 45, wherein the reporter group is selected from the group consisting of radioisotopes, fluorescent groups, luminescent groups, enzymes, biotin and dye particles.

52. A method for removing tumor cells from a biological sample, comprising contacting a biological sample with T cells that specifically react with a mammaglobin epitope selected from the group consisting of EYKELLQEFIDDNATTNAID (peptide 5A; SEQ ID NO: 4) and KLLMVLMLA (mgb 1; SEQ ID NO: 5), wherein the step of contacting is performed under conditions and for a time sufficient to permit the removal of cells expressing mammaglobin or a peptide epitope thereof from the sample.

53. The method of claim 52, wherein the biological sample is blood or a fraction thereof.

54. A method for inhibiting the development of breast cancer in a patient, comprising administering to a patient a biological sample treated according to the method of claim 52.

55. A method for stimulating and/or expanding T cells specific for mammaglobin, comprising contacting T cells with a peptide comprising at least 7, and no more than 30, consecutive amino acid residues of human mammaglobin, wherein the peptide comprises the sequence EYKELLQEFIDDNATTNAID (peptide 5A; SEQ ID NO: 4) or KLLMVLMLA (mgb 1; SEQ ID NO: 5), wherein the contact is performed under conditions and for a time sufficient to permit stimulation and/or expansion of T cells.

56. The method of claim 55, wherein the peptide comprises at least 9 consecutive residues of human mammaglobin.

57. The method of claim 55, wherein the peptide comprises at least 15 consecutive residues of human mammaglobin.

58. An isolated T cell population, comprising T cells prepared according to the method of claim 55.

59. A method for inhibiting the development of breast cancer in a patient, comprising administering to a patient an effective amount of a T cell population according to claim 58.

60. A method for inhibiting the development of breast cancer in a patient, comprising the steps of:

(a) incubating $CD4^+$ and/or CD8+ T cells isolated from a patient with a peptide comprising at least 7, and no more than 30, consecutive amino acid residues of human mammaglobin, wherein the peptide comprises the sequence

EYKELLQEFIDDNATTNAID (peptide 5A; SEQ ID NO: 4) or KLLMVLMLA (mgb 1; SEQ ID NO: 5), such that T cells proliferate; and

(b) administering to the patient an effective amount of the proliferated T cells, and thereby inhibiting the development of breast cancer in the patient.

61. The method of claim 60, wherein the peptide comprises at least 9 consecutive residues of human mammaglobin.

62. The method of claim 60, wherein the peptide comprises at least 15 consecutive residues of human mammaglobin.

63. A method for inhibiting the development of breast cancer in a patient, comprising the steps of:

(a) incubating $CD4^+$ and/or CD8+ T cells isolated from a patient with a peptide comprising at least 7, and no more than 30, consecutive amino acid residues of human mammaglobin, wherein the peptide comprises the sequence EYKELLQEFIDDNATTNAID (peptide 5A; SEQ ID NO: 4) or KLLMVLMLA (mgb 1; SEQ ID NO: 5), such that T cells proliferate;

(b) cloning at least one proliferated cell; and

(c) administering to the patient an effective amount of the cloned T cells, and thereby inhibiting the development of breast cancer in the patient.

64. The method of claim 63, wherein the peptide comprises at least 9 consecutive residues of human mammaglobin.

65. The method of claim 63, wherein the peptide comprises at least 15 consecutive residues of human mammaglobin.

66. A method for determining the presence or absence of breast cancer in a patient, comprising detecting the level of mammaglobin mRNA in sample of whole

blood, or a fraction thereof, obtained from a patient, wherein epithelial cells have been removed from the sample.

67. The method of claim 66, wherein the level of mammaglobin RNA is detected by:

(a) contacting the sample with an oligonucleotide that hybridizes to a polynucleotide encoding mammaglobin or a complement thereof;

(b) detecting in the sample an amount of a polynucleotide that hybridizes to the oligonucleotide; and

(c) comparing the amount of polynucleotide that hybridizes to the oligonucleotide to a predetermined cut-off value, and therefrom determining the presence or absence of breast cancer in the patient.

68. The method of claim 67, wherein the amount of polynucleotide that hybridizes to the oligonucleotide is determined using a polymerase chain reaction.

69. The method of claim 67, wherein the amount of polynucleotide that hybridizes to the oligonucleotide is determined using a hybridization assay.

70. A method for monitoring the progression of breast cancer in a patient, comprising:

(a) detecting the level of mammaglobin mRNA in sample of whole blood, or a fraction thereof, obtained from a patient, wherein epithelial cells have been removed from the sample;

(b) repeating step (a) using a sample obtained from the patient at a subsequent point in time; and

(c) comparing the amount of polynucleotide detected in step (b) to the amount detected in step (a) and therefrom monitoring the progression of the cancer in the patient.

71. The method of claim 70, wherein step (a) is performed by:

(i) contacting a biological sample obtained from a patient with an oligonucleotide that hybridizes to a mammaglobin polynucleotide; and

(ii) detecting in the sample an amount of a polynucleotide that hybridizes to the oligonucleotide.

72. The method of claim 71, wherein the amount of polynucleotide that hybridizes to the oligonucleotide is determined using a polymerase chain reaction.

73. The method of claim 71, wherein the amount of polynucleotide that hybridizes to the oligonucleotide is determined using a hybridization assay.